UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

SHREVEPORT DIVISION

RICKEY LEWIS	**CASE NO. 5:19-CV-00490**
VERSUS	**JUDGE TERRY A. DOUGHTY**
GE HEALTHCARE, INC., ET AL.	**MAG. JUDGE KAREN L. HAYES**

RULING

Before the Court is a Motion to Dismiss [Doc. No. 6] filed by Defendant McKesson Corporation ("McKesson"). For reasons explained below, the motion is GRANTED IN PART and DENIED INPART.

Background

On April 17, 2019, Plaintiff Rickey Lewis, a resident of Minden, Louisiana, filed the above-captioned lawsuit against Defendants General Electric Company; GE Healthcare, Inc.; GE Healthcare AS; and McKesson, for injuries he sustained following receipt of intravenous injections of Omniscan, a gadolinium-based contrast agent ("GBCA") manufactured by GEHC and distributed by McKesson. [Doc. No. 1, Compl. ¶¶ 1–15]. According to Lewis, he received the Omniscan injections in connection with several magnetic resonance imaging ("MRI") scans and soon after developed Gadolinium Deposition Disease ("GDD"), a disease that occurs in patients who have received a GBCA, with symptoms consistent with the toxic effects of retained gadolinium. *Id.*, ¶¶ 19-20. Lewis's alleged symptoms included, "but were not limited to . . . burning sensation; clouded mentation; confusion; weakness; fatigue; difficult and painful movement; inflammation; muscle cramps; numbness; tingling sensation; aching joints; lumps and rashes on the body." *Id.*, ¶ 19.

Lewis alleged that the Omniscan he received was manufactured by the "Defendants," which he defined as *all* the defendants in the suit. *Id.*, ¶¶ 12, 24. Lewis further alleged that, for years, Defendants knew, or should have known of the toxic effects of Omniscan on patients with normal or near-normal kidney function, yet they failed to warn healthcare providers and consumers of the risks associated with GBCAs. *Id.* ¶¶ 25-31. Lewis claims that he would not have received a GBCA, and would not have been afflicted with GDD, had he and/or his healthcare provider been warned of the risks. *Id.* ¶ 32.

Lewis's complaint asserted the following causes of action: (1) strict liability–failure to warn; (2) negligence; (3) negligent misrepresentation; (4) negligence per se; (5) breach of express warranty; (6) breach of implied warranty; (7) fraudulent misrepresentation and concealment; and (8) civil battery. *Id.*, ¶¶ 58-133. He seeks recovery for compensatory and punitive damages, plus attorney's fees and costs.

On May 29, 2019, McKesson filed the instant Motion to Dismiss, contending that (1) Lewis's allegations are conclusory and fail to meet the requisite pleading standard; (2) Lewis's claims premised on failure to warn are barred by federal preemption; and (3) Lewis failed to plead his causes of action for negligent misrepresentation and fraudulent misrepresentation/concealment with particularity under Fed. R. Civ. P. 9(b).

Lewis filed his oppositions to McKesson's Motion to Dismiss on June 28, 2019. [Doc. No. 16]. McKesson filed a reply brief on July 16, 2019. [Doc. No. 26]. Thus, the matter is ripe.

Standard of Review

The Federal Rules of Civil Procedure sanction dismissal where the plaintiff fails "to state a claim upon which relief can be granted." Fed.R.Civ.P. 12(b)(6). A pleading states a claim for

relief when, *inter alia*, it contains a "short and plain statement . . . showing that the pleader is entitled to relief . . ." Fed.R.Civ.P. 8(a)(2).

To withstand a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955 (2007)). A claim is facially plausible when it contains sufficient factual content for the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. *Plausibility* does not equate to *possibility* or *probability*; it lies somewhere in between. *See Iqbal, supra*. Plausibility simply calls for enough factual allegations to raise a reasonable expectation that discovery will reveal evidence to support the elements of the claim. *See Twombly*, 550 U.S. at 556, 127 S.Ct. at 1965.

Assessing whether a complaint states a plausible claim for relief is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal, supra* (citation omitted). A well-pleaded complaint may proceed even if it strikes the court that actual proof of the asserted facts is improbable, and that recovery is unlikely. *Twombly, supra*. Furthermore, "[t]he notice pleading requirements of Federal Rule of Civil Procedure 8 and case law do not require an inordinate amount of detail or precision." *Gilbert v. Outback Steakhouse of Florida Inc.*, 295 Fed. Appx. 710, 713 (5th Cir. Oct. 10, 2008) (unpubl.) (citations and internal quotation marks omitted). "Specific facts are not necessary; the statement need only 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Erickson v. Pardus*, 127 S. Ct. 2197, 2200 (2007) (quoting *Bell Atl.*, 127 S. Ct. at 1958). The complaint need not even "correctly specify the legal theory" giving rise to the claim for

relief. *Gilbert, supra*.[1] Although the court must accept as true all factual allegations set forth in the complaint, the same presumption does not extend to legal conclusions. *Iqbal, supra*. A pleading comprised of "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" does not satisfy Rule 8. *Id*. In addition, a court is compelled to dismiss an otherwise well-pleaded claim if it is premised upon an invalid legal theory. *Neitzke v. Williams*, 490 U.S. 319, 109 S.Ct. 1827 (1989).

When considering a motion to dismiss, courts generally are limited to the complaint and its proper attachments. *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 338 (5th Cir. 2008) (citation omitted). However, courts may rely upon "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice" – including public records. *Dorsey, supra*; *Norris v. Hearst Trust*, 500 F.3d 454, 461 n.9 (5th Cir. 2007) (citation omitted) (proper to take judicial notice of matters of public record). Furthermore, "[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to his claim." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-499 (5th Cir. 2000) (citations and internal quotation marks omitted).

Choice of Law

"[F]ederal courts sitting in diversity apply state substantive law and federal procedural law." *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 427 (1996); *see Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). This Court applies the choice of law rules of the forum state—Louisiana—to determine which state's law governs. *PHI, Inc. v. Rolls-Royce Corp.*, No.

[1] "Courts must focus on the substance of the relief sought and the allegations pleaded, not on the label used." *Gearlds v. Entergy Servs., Inc.*, 709 F.3d 448, 452 (5th Cir. 2013) (citations omitted).

CIV.A. 08-1406, 2010 WL 883794, at *5 (W.D. La. Mar. 9, 2010) (citing *Klaxon v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941)). Louisiana's choice of law rules are codified in Book IV of the Louisiana Civil Code. Article 3545 provides:

> [d]elictual and quasi-delictual liability for injury caused by a product, as well as damages, whether compensatory, special, or punitive, are governed by the law of this state: (1) when the injury was sustained in this state by a person domiciled or residing in this state; or (2) when the product was manufactured, produced, or acquired in this state and caused the injury either in this state or in another state to a person domiciled in this state.

In this products liability suit, Lewis alleged that he paid for and was injected with Omniscan in Louisiana. [Doc. No. 1, Compl. ¶ 17]. He suffered injury and was treated for Gadolinium Deposition Disease in Louisiana. *Id.* Therefore, because he is a Louisiana domiciliary *Id.*, ¶ ¶ 1, 16, who sustained injuries in Louisiana, his claims are governed by Louisiana law.[2]

To determine Louisiana law, "courts must begin every legal analysis by examining primary sources of law: the State's Constitution, codes, and statutes. Jurisprudence, even when it rises to the level of *jurisprudence constante,* is a secondary law source in Louisiana." *Ayala v. Enerco Grp., Inc.*, 569 F. App'x 241, 246 (5th Cir. 2014) (citation omitted). Thus, this court must look first to the LPLA, and only secondarily to judicial decisions (i.e., decisions of the Louisiana Supreme Court). *Id*., *see also Moore v. State Farm Fire & Casualty Co.*, 556 F.3d 264, 269 (5th Cir. 2009) (citation omitted).

[2] In addition, no party contests that the substantive issues raised by defendants' motions are governed by Louisiana law. *See In re Katrina Canal Breaches Litigation*, 495 F.3d 191, 206 (5th Cir. 2007) (deferring to the parties' agreement that Louisiana substantive law controlled); *Jefferson v. Lead Indus. Ass'n*, 106 F.3d 1245, 1250 (5th Cir. La. 1997) (applied Louisiana law where no party disputed that Louisiana law governed).

Discussion

The Louisiana Products Liability Act ("LPLA") "establishes the exclusive theories of liability for **manufacturers** for damage caused by their products," and a "claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in" the LPLA. LA. REV. STAT. 9:2800.52[3] (emphasis added).

Despite the more expansive allegations set forth in the Complaint, McKesson and Lewis agree that McKesson is not a manufacturer of Omniscan, but instead a distributor or seller of the product. Therefore, subject to certain exceptions not advanced here, Lewis's claims against McKesson are not subject to the LPLA. Rather, Louisiana law provides that a distributor or seller is liable in tort only if it knew or should have known that the product sold was defective and failed to declare it. *Delanzo v. ABC Corp.*, 572 So.2d 648, 651 (La. App. 5th Cir. 1990) (citations omitted); *State Farm Fire & Cas. Co. v. Delta Beverage Grp. Inc.*, 401 Fed. Appx. 955, 961 n.3 (5th Cir.2010) (citations omitted).

McKesson's principal argument is that most, if not all of plaintiff's state law tort claims are preempted by federal law when, as asserted here, it is "impossible for a private party to comply with both state and federal requirements." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 609; 131 S.Ct. 2567, 2572 (2011).

In *Mensing*, the Court observed that generic drug manufacturers had no means for unilaterally changing the labeling of their generic products. *In re Fosamax (Alendronate*

[3] The LPLA defines manufacturer as "a person or entity who is in the business of manufacturing a product for placement into trade or commerce." La. Rev. Stat. § 9:2800.53.

Sodium) Products Liab. Litig. (No. II), MDL 2243, 2012 WL 181411, at *2 (D.N.J. Jan. 17, 2012) (citing *Mensing, supra*). Instead, any changes in the generic labeling required action by the drug manufacturer and/or the FDA. *Id*. Further, "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* Consequently, the *Mensing* plaintiffs' failure-to-warn claims under state law were preempted "because it was impossible for the [generic] Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id*.

Although *Mensing* addressed the liability of generic drug manufacturers, McKesson contends that the same rationale may be extended to state law claims asserted against drug distributors who, like generic manufacturers, are not at liberty to change, modify, or extend the labeling. The Court agrees.

Omniscan is an FDA-approved product. [Doc. No. 1, Compl., ¶ 41]. Federal law requires FDA approval of a New Drug Application ("NDA") prior to marketing the drug in the United States. The company that owns and controls the NDA is referred to as the "applicant." 21 C.F.R. § 314.3(b). Following FDA approval of the new drug "only the applicant" may propose a change or supplement to the NDA. 21 C.F.R. § 314.71(a). GE Healthcare was the NDA applicant for Omniscan.[4] Accordingly, McKesson has no authority to unilaterally change or add to the Omniscan labeling. *In re Fosamax, supra*.

[4] *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020123 (last visited on March 12, 2020).

Because federal law will not permit McKesson to do what state law purports to require of it, Lewis's incompatible state law claims are preempted, i.e., his claims for strict liability–failure to warn; negligence; negligent misrepresentation; negligence per se; breach of express warranty; fraudulent misrepresentation and concealment; and civil battery.[5] *In re Fosamax, supra* (citation omitted); *Brazil v. Janssen Research & Dev. LLC*, 196 F.Supp.3d 1351, 1365 (N.D. Ga.2016); *Amos v. Biogen Idec Inc.*, 249 F.Supp.3d 690, 700 (W.D.N.Y.2017); *Stevens v. Cmty. Health Care, Inc.*, No. 200702080, 2011 WL 6379298, at *1 (Mass. Super. Oct. 5, 2011); *Pierik v. GE Healthcare, Inc.*, Order, No. 18-07733 (N.D. Ill. June 18, 2019) [doc. # 108] (dismissing state law failure to warn claims for risks or defects associated with Omniscan against McKesson, including claims for strict liability, negligence, negligent misrepresentation, negligence per se, breach of express warranty, and fraudulent misrepresentation).[6] However, the Court finds that Lewis's implied warranty or redhibition claim is not entirely preempted.

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[5]Plaintiff's civil law battery claim is premised upon plaintiff's lack of consent to having Omniscan retained in his body for months or years. [Doc. No. 1, Compl., ¶ 132]. In other words, McKesson committed a battery because it failed to disclose certain characteristics of Omniscan. In fact, under Louisiana law, medical battery is treated as a lack of informed consent. *Hamilton v. Negi*, CIV.A. 09-0860, 2014 WL 1388260, at *4 (W.D. La. Mar. 31, 2014), *aff'd*, 595 Fed. Appx. 346 (5th Cir.2014) (citation omitted). Lewis's is preempted.

[6]In his brief, Lewis cited contrary authority. *See, e.g., In re Actos® (Pioglitazone) Products Liab. Litig.*, No. 11-MD-2299, 2014 WL 12776173 (W.D. La. Sept. 5, 2014); *J.K.B. by Bennett v. Pfizer, Inc.*, No. 1305043, 2013 WL 12129385, at *6 (C.D. Cal. Nov. 4, 2013); *Dodich v. Pfizer Inc.*, No. 18-02764, 2018 WL 3584484, at *3 (N.D. Cal. July 26, 2018); and *In re Abilify (Aripiprazole) Products Liab. Litig.*, No. 16MD2734, 2018 WL 6258903, at *6 (N.D. Fla. Nov. 8, 2018). With the exception of *In re Actos*, however, the other decisions were resolved in the context of a motion to remand where the courts declined to consider the preemption argument. Further, the *In re: Actos* decision was issued after trial where evidence had been presented that the distributor played a role in the drug's labeling.

Under Louisiana law, a buyer has a warranty "against redhibitory defects, or vices, in the thing sold. A defect is redhibitory when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect." LA. CIV. CODE ART. 2520. Such a defect may give a buyer the right to obtain rescission of the sale, or, if the buyer would have still bought the product, but for a lesser price, a reduction of the purchase price. *Id*. As is made clear by the Louisiana Civil Code, recovery under a theory of redhibition is limited to purely economic loss and not recovery for personal injury. *Jefferson, supra*.[7] Plaintiff's redhibitory claim against McKesson remains viable and states a claim for relief.[8]

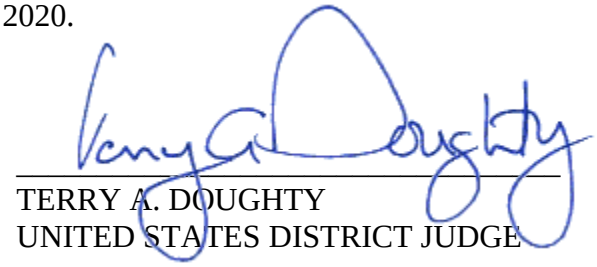
Conclusion

For the foregoing reasons, McKesson's Motion to Dismiss [Doc. No. 6] is GRANTED IN PART and DENIED IN PART. The motion is GRANTED as to Lewis's claims for strict liability: failure to warn, negligence, negligent misrepresentation, negligence per se, breach of express warranty, fraudulent misrepresentation/concealment, and civil battery, and these claims are DISMISSED WITH PREJUDICE. The motion is otherwise DENIED.

[7] If a seller knows that the thing he sells has a defect but fails to declare it, then the buyer also can recover damages and attorney's fees. LA. CIV. CODE ART. 2545. As noted by McKesson, however, a claim for "bad faith" damages against a seller likely is preempted given McKesson's inability to change or add to the drug's labeling requirements. *See Mensing, supra*.

[8] Given the finding that almost all of Lewis's claims against McKesson are preempted, the Court need not address the sufficiency of his allegations.

Monroe, Louisiana, this 13th day of March, 2020.



TERRY A. DOUGHTY
UNITED STATES DISTRICT JUDGE